

510(K) SUMMARY

K071908

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: Emergo Group Inc.
1705 S Capital of Texas Hwy Suite 500
Austin, TX 78746

AUG 23 2007

Date Summary Prepared: July 9, 2007

Contact Persons: Ian P Gordon
igordon@emergogroup.com

Device Name:

Trade Name(s): Doctor's Light LED Dental Curing Light
Classification Name: Ultraviolet Activator for Polymerization
Panel: Dental
Product Code: EBZ

Predicate Device Information:

Bluephase® marketed by Ivclar Vivodent, Incorporated, under K033520; and Turbo-Pen marketed by Apoza Enterprize Co., Ltd.

Device Description:

Doctor's Light LED Dental Curing Light is a hand-held polymerization light intended for use in curing dental composites. This product uses a rechargeable Li-ion Battery for cordless operation.

Intended Use:

This device is intended for curing dental composites using visible light.

Comparison to Predicate Device(s):

This device is equivalent to the predicate devices in intended use and technological characteristics, including:

- Light source
- Power source
- Wavelength
- Materials
- Light intensity
- Peak wavelength
- Depth of cure

Performance Test Data and Conclusions:

This device meets consensus standards IEC 60601-1 for electrical safety and IEC 60601-1-2. Bench testing was also conducted to demonstrate performance specifications.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 23 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Good Doctors Company, Limited
C/O Mr. Ian P. Gordon
Senior Vice President
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K071908

Trade/Device Name: Doctor's Light LED Dental Curing Light
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: July 05, 2007
Received: July 10, 2007

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

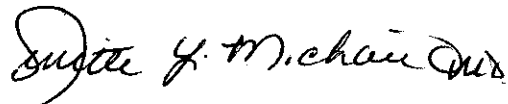
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", written in a cursive style.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Premarket Notification – Doctor's Light LED Dental Curing Light

Indications for Use

510(k) Number (if known): K071908

Device Name: Doctor's Light LED Dental Curing Light

Indications for Use:

Curing of dental composites using visible light.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Miley for KSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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